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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/394,902	09/13/1999	Steven L. Stice	000270-026	5113
909	7590	01/27/2004	EXAMINER	
PILLSBURY WINTHROP, LLP			TON, THAIAN N	
P.O. BOX 10500			ART UNIT	
MCLEAN, VA 22102			PAPER NUMBER	

1632

DATE MAILED: 01/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/394,902

Applicant(s)

STICE ET AL.

Examiner

Thai-An N Ton

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41,42,44,46,47 and 49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41,42,44,46,47 and 49 is/are rejected.
- 7) ☒ Claim(s) 49 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Applicants' After-Final Amendment, filed 1/9/04, has been entered. Claims 41, 42, 44, 46, 47 and 49 are pending and under current examination.

The finality of the prior Office action, mailed 7/1/03, is withdrawn.

Claim Objections

Claim 49 is objected to because of the following informalities:

- 1) The term *differentiated* is misspelled in step (ii) of the claim;
- 2) In part (iii) of the claim, there is no article before the term oocyte, and no verb after the term. Correction is suggested so that the line reads:
(iii) removing the endogenous oocyte nucleus if the oocyte is not previously enucleated.

Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 41, 42 and 44 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, 6 and 18 of U.S. Patent No. 6,235,970. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to methods for producing CICM cell lines. The instant claims are drawn to methods for producing pluripotent porcine CICM cell lines and the '970 claims are drawn to methods for producing a mammalian CICM cell line, and in particular embodiments, porcine CICM cell lines. Thus, the instant claims are made obvious by the '970 claims.

Claim 49 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 and 21 of U.S. Patent No. 6,215,041. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to methods for cloning porcine. The instant claims are directed to methods for cloning a porcine fetus or live offspring comprising activating a porcine oocyte that is optionally enucleated, transferring a differentiated pig cell or nucleus into the porcine oocyte to produce an NT unit, removing the endogenous oocyte nucleus if the oocyte is not

previously enucleated and transferring the NT unit, optionally after a culture step, into a female porcine to produce a porcine fetus or animal. The '041 claims are directed to methods of cloning a non-human mammal by NT, by introduction of a non-human mammalian donor cell or cell nucleus into an enucleated oocyte of the same species to form an NT unit, implantation of the NT unit into the uterus of a surrogate mother of the same species, wherein the donor cell or cell nucleus is a non-quiescent somatic cell. The instant claims state that the donor cell is a differentiated cell, and the instant specification provides teachings to show that differentiated cells include non-quiescent cells. See p. 8, lines 10-11. Thus, the instant claims are obvious over the '041 claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 41, 42, 44, 46, 47 and 49 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods for producing a pluripotent porcine CICM cell line comprising (i) inserting a desired differentiated pig cell or cell nucleus of a differentiated pig cell into an enucleated pig oocyte under conditions suitable for the formation of an NT unit, activating the resulting NT unit, culturing the activated NT unit until a discernible trophectoderm

and ICM is obtained, and culturing the ICM cells to obtain a porcine CICM cell line which is pluripotent and may be maintained indefinitely in tissue culture, and methods for cloning a porcine fetus or live offspring comprising: (i) activating an optionally enucleated porcine oocyte, (ii) transferring a differentiated pig cell or pig nucleus into said porcine oocyte after or approximately simultaneous to activation to produce an NT unit, (iii) removing the endogenous oocyte nucleus and transferring the NT unit into the uterus of a female porcine and permitting the NT unit to develop into a cloned porcine fetus or offspring, does not reasonably provide enablement for methods for producing pluripotent porcine CICM cell lines without obtaining inner cell mass cells, and methods for producing a cloned porcine fetus or offspring without transfer of the NT unit into a female porcine and further development of the NT unit to produce a cloned porcine fetus or offspring. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claimed methods for producing a pluripotent porcine CICM cell line are not enabling because they do not provide a step in the independent claim for obtaining of inner cell mass cells. The specification teaches that the cells that would be cultured to produce the CICM cells are those from the inner most portion of the NT unit (*i.e.*, the inner cell mass cells). See p. 39, lines 14-15. Thus, although claim 42 provides a step of culturing the activated NT unit until a discernible

trophectoderm and ICM is obtained, this step is not optional, but required to enable the claimed methods. In order to culture inner cell mass cells to produce the claimed CICM cells, it would be required that the NT unit be developed sufficiently to have ICM cells, which could be isolated and then cultured.

The claimed methods for producing a cloned porcine fetus or live offspring (claim 49) is not enabled because the steps state that the NT unit is optionally transferred into a female porcine to produce a porcine fetus or offspring. In order to further development, it is known to those of skill in the art that the NT unit *must* be transferred into the uterus of a female of the same species; thus, in order to produce either a fetus or a live offspring, the step of transferring and allowing further development of the NT unit is required.

Accordingly, in view of the specification's lack of teachings or guidance with regard to producing porcine CICM cells lines without culturing the activated NT unit to obtain inner cell mass cells, and the lack of teaching or guidance provided by the specification with regard to production of a cloned porcine fetus or live offspring without transfer of the activated NT unit into the uterus of a female porcine, it would have required undue experimentation for one of skill in the art to carry out the claimed methods.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Thaian N. Ton whose telephone number is (571) 272-0736. The Examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the Examiner be unavailable, inquiries should be directed to Amy Nelson, Acting SPE of Art Unit 1632, at (571) 272-0804. Any administrative or procedural questions should be directed to William Phillips, Patent Analyst, at (571) 272-0548. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

TNT

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